

REMARKS

Reconsideration of this application is respectfully requested.

The Examiner's comments regarding the requirement for restriction are noted. The Examiner is again requested to reconsider his position and rejoin the subject matter of Group I-IV. As indicated on page 31 of the application DDRT2 (SEQ ID NO:34 (Group I)), DDRT7 (SEQ ID NO:50) (Group II)), DDRT16 (SEQ ID NO:40 (Group III)) and DDRT26 (SEQ ID NO:14 (Group IV)) are all derived from the same predicted gene, F35E8.11. That being the case, it is inconceivable that a thorough search of the elected Group would not include the subject matter of non-elected Groups I, II and IV.

In addition to the above, the Examiner's attention is directed to the fact that the present requirement for restriction fails to comply with the spirit of the Commissioner's Notice of November 19, 1996. The Commissioner indicated in that Notice that the Patent Office was attempting to strike a balance between aiding the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office. To that effect, the Patent Office had determined that, in most cases, up to ten independent and distinct nucleotide

sequences would be examined in a single application without restriction. With that in mind, the Examiner is again requested to withdraw the requirement for restriction at least as between Groups I to IV.

The Examiner's comments regarding the possible filing of Petition to the Commissioner for review of the restriction requirement are noted and Applicants intend to pursue that option should the Examiner refuse to reformat the restriction requirement as requested above.

Claims 7, 11 and 15 stand rejected under 35 USC 101 as allegedly lacking utility. The rejection is traversed.

As indicated above, DDRT16 is derived from the *C. elegans* gene F35E8.11. As indicated in Table II of Example 2, greater than a 4-fold increase in DDRT16 mRNA level was observed following cadmium exposure. The responsiveness of the gene from which DDRT16 derives to a stressor such as cadmium makes it useful in the context of a biomonitor. As indicated on page 1 of the application, cadmium is a serious occupational and environmental toxin. Accordingly, this utility (clearly set forth on page 12 of the subject application) has profound "real world" application.

The Examiner's attention is also directed to the attached article of Liao et al (2002). The cadmium-

responsive gene described is designated *cdr-1* (note the defined relationship to DDRT2, DDRT7, DDRT16 and DDRT26 at page 42050, left column). The cell-specific expression of *cdr-1* is shown in Fig. 6 and the data provided serve underscore the utility as a biomonitor, as indicated above.

In further support of their position, Applicants submit herewith an article by Cioci et al (2000) that describes the usefulness of transgenic strains of *C. elegans* as biomonitors.

In view of the above and attached, reconsideration is requested.

Claims 7, 11 and 15 stand rejected stand rejected under 35 USC 112, first paragraph, on the basis that one would not know how to use the claimed invention. The rejection is traversed.

As indicated above, one utility of the claimed invention is in the context of a biomonitor. The Examples make clear that, on exposure to cadmium, mRNA levels are significantly increased. The disclosure at page 12 describes means for assaying levels of expression (see also Examples). Such approaches are standard in the art. At page 13 of the application, the use of transgenic organisms comprising cadmium-responsive sequences as biomonitors to measure the levels of bioavailable cadmium is described.

The application provides all that is necessary - the identification of the cadmium-responsive sequence and means for measuring the level of expression upon exposure to the stressor. Nothing more should be required to satisfy the requirement of 35 USC 112, first paragraph. Reconsideration is thus requested.

Claim 15 stands rejected under 35 USC 112, first paragraph, as allegedly lacking written description. The rejection is traversed.

Claim 15 is drawn to *C. elegans* the genome of which has been engineered to include the nucleic acid of claim 7 (DDRT16). That Applicants had possession of this subject matter at the time of filing is evident from the following:

i) Original claim 4 is drawn to a *C. elegans* the genome of which has been engineered to include a cadmium-responsive gene.

ii) Pages 13 and 14 of the application describe the *C. elegans* of original claim 4.

iii) Table II demonstrates that there is greater than a 4-fold increase in DDRT16 mRNA level following cadmium exposure (that is, that it is cadmium-responsive).

The foregoing provides a clear written description of the *C. elegans* of claim 15. Accordingly, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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